

4-8.000

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4-8.010 Introduction

The Civil Division's Office of Consumer Litigation (OCL) is responsible for criminal and civil litigation and related matters arising under the Federal Food, Drug, and Cosmetic Act (FDCA) and other federal statutes that protect public health and safety. The Office also enforces, through civil actions, statutes that regulate unfair and deceptive trade practices, and it defends the government programs and policies in consumer-related areas.

OCL, created in 1971, has been central in developing the caselaw under the various esoteric statutes over which OCL has jurisdiction pursuant to 28 C.F.R. § 0.45(j). These statutes give rise to felony and misdemeanor prosecutions, as well as civil cases. USAOs should contact OCL as soon as possible after receiving a case in one of these areas for advice and assistance, and to obtain authorization to file the case.

OCL serves several functions for cases developed by USAOs: (1) to ensure that Assistant United States Attorneys do not overlook unique policy or factual concerns that frequently affect litigation under OCL's statutes; (2) to ensure that Assistant United States Attorneys do not have to "reinvent the wheel," when OCL already has jury instructions, briefs, and other pleadings on relevant points; and (3) to obtain the Assistant Attorney General's approval that is needed before filing cases in these areas.

When a client agency refers a case to the Department of Justice, OCL receives the referral and will either retain it or ask a USAO to handle the case. However, in two areas Assistant United States Attorneys sometimes

receive cases directly from investigative agencies without OCL's involvement. These are cases under the FDCA and the odometer tampering statutes. Accordingly, the focus below will be to provide guidance and models in these two areas. USAOs should consult with OCL when cases are first received in either area.

For a complete listing of the statutes assigned to OCL in 28 C.F.R. § 0.45(j) see the Civil Resource Manual at 101.

4-8.100 Persons to Contact at OCL

Thirolf, Eugene, Director, (202) 307-3009.

McDade, Lawrence, Deputy Director, (202) 307-0138.

Jost, Kenneth, Assistant Director, (202) 307-0048.

Lahaie, Henry, Assistant Director, (202) 307-0053.

See the Civil Resource Manual at 102 for an OCL roster.

4-8.200 Federal Food, Drug, and Cosmetic Act Litigation

FDCA matters can be initiated in USAOs by an agent seeking a search warrant, a grand jury subpoena, or a prosecution. These matters are not always coordinated among all affected parties. Accordingly, notifying OCL of such a contact may be the only way to ensure that USAOs are fully informed of the context in which a request arises -- a context that may involve other investigative agencies or cases. In addition, FDA initiates civil seizure actions under the FDCA by direct referral to USAOs.

Intense outside scrutiny of FDCA prosecutions has occurred in recent years. This adds to the general need for consistency in how similar cases in different locations are charged. OCL can bring expertise to FDCA matters that helps maintain critical consistency in enforcement decisions.

The discussions below focus on the major types of FDCA cases, and significant issues that are common to most FDCA matters.

4-8.205 Felony Prosecutions -- "Intent to Defraud"

Any person who commits a prohibited act set forth in 21 U.S.C. § 331 violates the FDCA. A person committing such an act "with the intent to defraud or mislead" is guilty of a three-year felony. 21 U.S.C. § 333(a)(2). Intent to defraud or mislead can be established by demonstrating a fraud upon either the ultimate consumer of the product, or upon the FDA, or both. That is, a person whose fraudulent conduct is directed at the FDA, as is common in black market and other contexts, is guilty of felony behavior, and should be prosecuted on that basis.

See the Civil Resource Manual at 103, and section IV (C) of the trial memorandum reproduced in the Civil Resource Manual at 27.

4-8.210 "Park" Misdemeanor Liability

A misdemeanor conviction under the FDCA, unlike a felony conviction, does not require proof of fraudulent intent, or even of knowing or willful conduct. OCL attempts wherever possible to bring felony charges to deal with fraudulent behavior. Nevertheless, misdemeanor liability can attach to behavior that, due to lack of proof or other problems with a case or defendant, may not merit felony prosecution. See Civil Resource Manual at 104 for a discussion of misdemeanor elements, 105 and 106 for potential jury instructions, and 107 for a brief discussing a similar principle in other contexts.

4-8.215 Grand Jury Subpoena Practice

For a model subpoena, and practice tips for an FDCA investigation, see Civil Resource Manual at 108.

4-8.220 FDCA Criminal Prosecution of "Black Marketeers"

Several black markets in unapproved pharmaceuticals generate direct agent to USAO contacts. OCL should be advised when such matters are initiated. Common matters include drugs such as GHB, Human Growth Hormone, and various animal drugs. Agents sometimes suggest conducting "buy-bust" scenarios as are common with controlled substances. Important guidance in these areas, and sample pleadings, are included in the Civil Resource Manual at 15 *et seq.*

4-8.225 Prosecutions of Manufacturers of Drugs, Devices, and Biologics

FDA commonly coordinates complex investigations involving the industries it regulates through OCL. Nevertheless, USAOs may receive such matters directly. OCL should be notified when this occurs for advice and assistance. Issues regarding medical devices and adulteration or misbranding claims are discussed in the Civil Resource Manual at 109.

4-8.230 The Prescription Drug Marketing Act ("PDMA")

The PDMA deals with a "grey market" in prescription drugs. This grey market includes diverted sample drugs and diverted drugs originally sold to hospitals. The PDMA is codified in the FDCA, with prohibited acts listed at 21 U.S.C. § 331(t). When contacted by an investigative agency concerning a potential PDMA matter, USAOs should contact OCL. The PDMA is a complex statute with numerous exceptions. OCL will provide advice and assist in developing an effective case strategy.

For a very general description of the PDMA, see the Civil Resource Manual at 113. See the Civil Resource Manual at 114 *et seq.* for model charging documents.

4-8.235 "Food Fraud" Prosecutions

OCL has litigated numerous prosecutions in which a food was "stretched" with cheaper ingredients that are difficult to detect, leading consumers to pay higher prices for lower quality foods. Where evidence of fraud exists, the deliberate cheating of consumers in this fashion should be prosecuted under the felony provisions of the FDCA, or as mail or wire fraud, or both. Sample indictments are included in the Civil Resource Manual at 118 *et seq.* See the Civil Resource Manual at 124 *et seq.* for sample jury instructions. Also included in the Manual at 126 are practice tips and a brief regarding one use of evidence of scientific testing in this type of case.

4-8.240 Motions Commonly Filed

Defendants commonly challenge FDCA indictments alleging a variety of defects that the courts have held do not exist. The Civil Resource Manual contains a number of sample briefs opposing several such motions.

Civil Resource Manual at 127 *et seq.* Responses to motions to strike surplusage from indictments. These motions challenge primarily the introductory paragraphs of FDCA indictments.

Civil Resource Manual at 131 and 132. Responses to motions to dismiss counts or require or require election due to multiplicity where the adulteration and and misbranding of a food or drug are alleged in separate counts. This is the common method of charging, and the courts have accepted it, so it should be continued. (If an

indictment were to allege adulteration and misbranding in the same count, the defendant would allege that the counts were duplicitous. Accordingly, the well-worn path of charging separate counts, which has successfully been defended, should be followed.).

Civil Resource Manual at 133. This memorandum, in addition to dealing with a multiplicity challenge, lays out differences between violations of the FDCA contained in 21 U.S.C. § 331(a) and § 331(k).

Civil Resource Manual at 134 and 135. This trial brief sets forth the elements of violations of the FDCA contained in 21 U.S.C. § 331(a) and § 331(k). It also deals with evidentiary issues including the admissibility of summaries, foreign records, plea agreements, and scientific evidence, and chain of custody issues.

Civil Resource Manual at 136. Opposition to defense motions including to dismiss due to purported due process/vagueness, "Van Liew," and "Minarik" problems.

Civil Resource Manual at 137. An exhaustive analysis of Minarik.

Civil Resource Manual at 138 and 139. Defendants may allege that FDA acquiesced in their violations, or that the government engaged in selective prosecution in choosing whom to prosecute. These samples support government motions in limine to preclude evidence or argument at trial on these issues.

Civil Resource Manual at 140. Willfulness is not an element of an FDCA felony, and the good faith defense is thus somewhat limited.

Civil Resource Manual at 141. A sentencing memorandum discussion demonstrating that a veterinarian who dispenses drugs unlawfully should receive an abuse of trust enhancement under U.S.S.G. § 3B1.3.

4-8.245 Jury Charges

The Civil Resource Manual contains a number of sample jury instructions. Note that some of the instructions cover topics such as "interstate commerce" and other definitions which have broader applicability than the specific type of case identified.

Civil Resource Manual at 24 and 25. Animal drug cases.

Civil Resource Manual at 106. Misdemeanor instruction defining "responsible person."

Civil Resource Manual at 105. Misdemeanor instructions in adulterated food case. Request No. 5 deals with the issue of liability under a Park theory.

Civil Resource Manual at 124. Food fraud case.

4-8.250 Sentencing Considerations in FDCA Prosecutions

Any violation of the FDCA committed with "intent to defraud or mislead" is a felony. 21 U.S.C. § 333(a)(2). In virtually all felony FDCA prosecutions, U.S.S.G. § 2F1.1 is the applicable Chapter Two offense guideline by virtue of the cross-reference at U.S.S.G. § 2N2.1(b)(1). Section 2N2.1 applies to FDCA misdemeanors, which do not involve fraud. In structuring any FDCA investigation, consideration must be given to issues affecting sentencing, such as identifying the persons defrauded and the risk to public health. Particular effort should be made to learn the full extent of the fraud. Defendants have been sentenced to significant incarceration based largely on the amount of fraud. For a sample analysis estimating loss based on savings to defendants see Civil Resource Manual at 142. For a discussion of significant factors that affect sentencing in FDCA cases, see the Civil Resource Manual at 143. For an appellate brief regarding loss that takes account of recent significant cases analyzing loss in various FDCA drug contexts, see the Civil Resource Manual at 144.

4-8.255 Indictments and Information

The following sample charging documents for FDCA cases are in the Civil Resource Manual:

Civil Resource Manual at 121. *United States v. Mays*, an indictment with seven defendants and 33 counts (orange juice concentrate stretched with sugar).

Civil Resource Manual at 118. *United States v. Peninsular Products*, an indictment with nine defendants, 33 counts, (orange juice concentrate stretched with sugar; unlabeled preservatives; false declaration to grand jury).

Civil Resource Manual at 123. *United States v. Rubino*, one defendant, two counts (olive oil stretched with canola oil).

Civil Resource Manual at 17. GHB prosecution (potential charges).

Civil Resource Manual at 111. *United States v. Cottone*, one defendant (medical device violations; false statement to agency).

Civil Resource Manual at 112. *United States v. Chan*, one defendant (medical device violation focused on false statements and obstruction of justice).

Civil Resource Manual at 22. *United States v. Van Damme*, two defendants, seven counts (animal drug prosecution with conspiracy, adulterated and misbranded drug counts, and an unregistered drug manufacturing facility count).

Civil Resource Manual at 23. *United States v. Minneman*, one defendant, four counts (animal drug prosecution with conspiracy and misbranded drug counts).

4-8.260 Seizures Under the FDCA

FDA routinely recommends seizure actions under the FDCA (authorized by 21 U.S.C. § 334) by direct referral to USAOs. Most of these actions are routine, involving filthy storage conditions at food warehouses, and similar clear violations of the FDCA. However, some seizure recommendations are based on novel or difficult theories under the FDCA. USAOs should notify OCL if they receive such a referral, or if any seizure action is contested. Caselaw and procedures applicable to FDA seizure cases are discussed in the Civil Resource Manual at 146 *et seq.*

4-8.300 Odometer Fraud Prosecutions

OCL should be contacted when an odometer fraud investigation is opened so that information regarding potential overlaps with other cases can be shared. OCL should also be provided a copy of any proposed indictment or information at least one week before presentation or filing, so that necessary approvals can be obtained. In general, unless a USAO requests more active assistance on such investigations, OCL will merely monitor the case thereafter. See the Civil Resource Manual at 149 for a discussion of the agencies involved in these matters, who should be contacted, and investigative resources available through OCL.

4-8.305 Recodification of the Odometer Fraud Statutes

Effective July 5, 1994, the odometer tampering statutes were recodified from Title 15, U.S.C., to Title 49. The change was not substantive, though the statutes were reworded. Charging documents for offenses occurring on or after July 5, 1994, should cite Title 49 rather than Title 15. See the Civil Resource Manual at 150 for a detailed description of the recodification, and at 151 for the text of the former Title 15 offenses.

4-8.310 From Investigating to Sentencing

Included in the Civil Resource Manual are a variety of materials that will serve as resources and models for every step in an odometer fraud case. Included are guides for investigations, computerization help, sample indictments, trial briefs, responses to motions, and matters relevant to sentencing.

50	Other	*Odometer tampering implicates	*Civil Resource Manual	5
50	Offenses	*several federal criminal	*at 152	5
5	Commonly	*statutes. It is generally	*	5
5	Charged	*desirable to charge defendants	*	5
5		*with offenses in addition to	*	5
5		*odometer fraud. Such charges	*	5
5		*more accurately depict the	*	5
5		*totality of the illegal conduct,	*	5
5		*and provide theories of	*	5
5		*liability that may lead to	*	5
5		*conviction where, for example, a	*	5
5		*jury is not convinced that a	*	5
5		*defendant was responsible for	*	5
5		*some aspect of the conduct	*	5
5		*reflected in a single count.	*	5
5		*Included is a discussion of the	*	5
5		*types of charges that can be	*	5
5		*alleged with odometer tampering	*	5
5		*charges, along with some	*	5
5		*pertinent citations.	*	5

6	L	L	L
5Subpoenas	*Forensic evidence is frequently	*Civil Resource Manual	5
5to	*effective. Targets often forge	*at 153.	5
5"Targets" --	*other people's writing to	*	5
5Forensic	*conceal their role in a scheme.	*	5
5Evidence	*It is advisable to obtain	*	5
5	*handwriting exemplars from	*	5
5	*targets. In addition,	*	5
5	*fingerprints may remain on a	*	5
5	*fraudulent document. No	*	5
5	*Fifth Amendment privilege	*	5
5	*protects handwriting,	*	5
5	*fingerprints, or photographs.	*	5
5	*There should be no reluctance to	*	5
5	*subpoena such items. Sample	*	5
5	*language for a subpoena is	*	5

5	*included.	*	5
5	Subpoenas	*It is good practice to subpoena	5
5	to "Targets"	*targets for records relating to	5
5	Required	*purchase and sale of	5
5	Records	*automobiles, including odometer	5
5		*statements. Because such	5
5		*documents are "required records"	5
5		*for a used car dealer, targets	5
5		*cannot assert their Fifth	5
5		*Amendment privilege in resisting	5
5		*a subpoena seeking such	5
5		*materials.	5
5	Computerizing	*Odometer fraud investigations	5
5	Investigative	*frequently involve hundreds or	5
5	Records	*thousands of vehicles. OCL has	5
5		*developed a computer database	5
5		*for use in organizing and	5
5		*tracking these investigations.	5
5		*The requirements for its use are	5
5		*that the user have at least an	5
5		*IBM-compatible "386" computer,	5
5		*and Windows. Users do not need	5
5		*any particular database	5
5		*software. This database is	5
5		*available free of charge from	5
5		*OCL.	5
5	Indictments	*Included are sample indictments	5
5		*or informations.	5
5	Trial	*Trial briefs can explain unusual	5
5	Briefs	*aspects of odometer fraud trials.	5
5		*The samples explain evidence from	5
5		*auto auctions, dealer records,	5
5		*and titling documents and	5
5		*procedures. They also lay out	5
5		*theories such as Pinkerton, and	5
5		*evidentiary matters, such as that	5
5		*title histories are self-	5
5		*authenticating and the admissibi-	5
5		*lity of summary charts, plea	5
5		*agreements, and video and audio	5
5		*plea agreements, and video and	5
5		*audio tapes.	5
5	Jury	*Sample jury instructions from	5
5	Instructions	*odometer tampering cases are	5
5		*included.	5
5	Commonly	*Deals with the sufficiency of	5
5	Filed	*proof of mailing as to	5
5	Defense	*conspiracy to commit mail fraud	5
5	Motions	*counts, and with the adequacy of	5
5		*a state department of motor	5
5		*vehicle mailing of a title as	5
5		*satisfying the mailing element.	5

[illegible]

